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EXAMINER	
SUNDARARAMAN, VIKRAM P	

ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,863	HOSKONEN ET AL.	
	Examiner	Art Unit	
	Vikram P. Sundararaman	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/27/2004
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. **Claims 3, 5, 6, 13, 15, 16, 23, 25, 26, 29, 30, and 31** are objected to because of the following informalities: The claims cited above lack proper antecedent basis for specific claimed limitations. (e.g. "wherein three of the electrodes") As cited in the claims upon which these cited claims are dependent, an array only requires two electrodes. These claims, however, recite "three of the electrodes." It is clear that these claims lack proper antecedent basis for reciting three electrodes. It is suggested that applicant recite either: (a) in the claims upon which these claims are dependent or (b) in the objected claims themselves, that "the array includes at least three electrodes, wherein three of the electrodes..." Appropriate correction is required.

Claim Rejections - 35 USC § 101

2. **Claims 2-3, 5-9,12-19, 22-23, 25-26, and 28-32** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In each instance, the human body is non-statutory subject matter and cannot positively be claimed. To overcome these rejections, for example, Lines 2-3 of Claim 3 should be replaced with "a first of the three electrodes *is capable* of being located on the temple area," Line 4 of the claim should be replaced with, "a second electrode *is capable* of being located above the eye," Lines 5-6 of the claim should be replaced with "*which is capable of being* located between the eyebrows of the patient at the center of the

forehead, about 4 cm above the nose," and Lines 7-8 should be replaced with "a fourth electrode of the array of electrodes *is capable of being* located below the eye."

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 4 and 24** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear from the recitation "wherein the electrodes, " in Line 1 of these claim, which electrodes are being referred to specifically.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claim 1** is rejected under 35 U.S.C. 102(b) as being anticipated by Lisiecki, US 6,083,156, hereinafter referred to as "Lisiecki."

7. As to **Claim 1,** Lisiecki teaches **a sensor arrangement,** *"portable integrated physiological monitoring system,"* that includes: **a base element,** *"a chassis of electronic components (electronics unit) that acquisitions information from the sensors and communicates this information to a portable personal computer"* [Column 3, Line 67

– Column 4, Line 3]; **an array of electrodes,** *"a plethora of physiological sensors and auxiliary devices"* [Column 3, Lines 66-67]; **an optical sensor,** *"a finger pulse oximeter, 110,"* [Column 7, Lines 5-6]; and **are connected to a series of connectors attached to the base element,** [*See FIG 1.*] It is noted that the phrase, "for monitoring substances in tissues" is a recitation of intended use. It is therefore noted that Lisiecki teaches a device with an optical sensor that is capable of monitoring substances in tissues.

8. As to **Claim 2**, Lisiecki teaches the arrangement of Claim 1, **wherein a first and a second electrode of the array of electrodes are NMT stimulus electrodes,** *"Alligator clips, 106, consist of ten miniature alligator clips that attach to a human subject via disposable tab electrodes. These clips can also be used for acquisition of... neuromuscular signals from a human subject. Alligator clips, 108, consist of two miniature alligator clips that attach to a human subject via disposable tab electrodes. These clips apply high voltage pulses to the human subject stimulation associated with nerve conduction studies."* [Column 6, Line 62 – Column 7, Line5 & See FIG 1]] It is noted that while the specific placement of the disposable electrode tabs and corresponding alligator clips are not taught, that it is possible to arrange the same in the manner described in Claim 2.

9. **Claims 3 and 5** are rejected as Lisiecki teaches the arrangement of Claims 1 or 2, and as the limitation, **wherein three of the electrodes of the array of electrodes are used to measure EEG and EMG,** merely states an intended use of the structure. That aside, Lisiecki teaches, *"FIGS. 1 and 2 show only three of these clips for illustrative*

purposes however, ten of them are required for acquisition of a 12-lead electrocardiogram. These clips can also be used for acquisition of electroencephalographic and neuromuscular signals from a human subject." [Column 6, Line 64 – Column 7, Line 1] It is noted that while the specific placement of the disposable electrode tabs and corresponding alligator clips are not taught, that it is possible to arrange the same in the manner described in Claim 3.

10. As to **Claim 4, wherein the electrodes are used to measure NMT response,** is merely a statement of intended use and does not further limit the claims. In any event, Lisiecki teaches the arrangement of Claim 3, *"these clips can also be used for acquisition of electroencephalographic and neuromuscular signals from a human subject."* [Column 6, Line 66 – Column 7, Line 1]

11. As to **Claim 6**, it is noted that it is possible to position the combination of the disposable electrode tabs and miniature alligator clips in the configuration described in this claim.

12. As to **Claim 10**, Lisiecki teaches the arrangement of Claim 1, **wherein the optical sensor is a SpO2 sensor.** FIG 1 clearly indicates that sensor 110 is a connected to a SpO2 terminal. [See FIG 1.]

13. As to **Claim 21,** Lisiecki teaches, **a sensor arrangement,** *"portable integrated physiological monitoring system"* [Title] that includes: **a base element,** *"a chassis of electronic components (electronics unit) that acquisitions information from the sensors and communicates this information to a portable personal computer"* [Column 3, Line 67 – Column 4, Line 3]; **an array of electrodes,** *"a plethora of physiological sensors and*

auxiliary devices" [Column 3, Lines 66-67]; **an optical sensor,** *"a finger pulse oximeter, 110,"* [Column 7, Lines 5-6]; and **are connected to a series of connectors attached to the base element,** [*See FIG 1.*] Lisiecki further teaches **wherein a first and a second electrode of the array of electrodes are NMT stimulus electrodes,** *"Alligator clips, 106, consist of ten miniature alligator clips that attach to a human subject via disposable tab electrodes. These clips can also be used for acquisition of... neuromuscular signals from a human subject. Alligator clips, 108, consist of two miniature alligator clips that attach to a human subject via disposable tab electrodes. These clips apply high voltage pulses to the human subject stimulation associated with nerve conduction studies."* [Column 6, Line 62 – Column 7, Line5 & See FIG 1]

14. As to **Claim 22**, Lisiecki teaches the arrangement of Claim 21, **wherein a first and a second electrode of the array of electrodes are NMT stimulus electrodes,** *"Alligator clips, 106, consist of ten miniature alligator clips that attach to a human subject via disposable tab electrodes. These clips can also be used for acquisition of... neuromuscular signals from a human subject. Alligator clips, 108, consist of two miniature alligator clips that attach to a human subject via disposable tab electrodes. These clips apply high voltage pulses to the human subject stimulation associated with nerve conduction studies."* [Column 6, Line 62 – Column 7, Line5 & See FIG 1] It is noted that while the specific placement of the disposable electrode tabs and corresponding alligator clips are not taught, that it is possible to arrange the same in the manner described in Claim 22.

15. **Claims 23 and 25** are rejected as Lisiecki teaches the arrangement of Claims 21 or 22, and as the limitation, **wherein three of the electrodes of the array of electrodes are used to measure EEG and EMG,** merely states an intended use of the structure. That aside, Lisiecki teaches, *"FIGS. 1 and 2 show only three of these clips for illustrative purposes however, ten of them are required for acquisition of a 12-lead electrocardiogram. These clips can also be used for acquisition of electroencephalographic and neuromuscular signals from a human subject."* [Column 6, Line 64 – Column 7, Line 1] It is noted that while the specific placement of the disposable electrode tabs and corresponding alligator clips are not taught, that it is possible to arrange the same in the manner described in Claim 23.

16. As to **Claim 24, wherein the electrodes are used to measure NMT response,** is merely a statement of intended use and does not further limit the claims. In any event, Lisiecki teaches the arrangement of Claim 23, *"these clips can also be used for acquisition of electroencephalographic and neuromuscular signals from a human subject."* [Column 6, Line 66 – Column 7, Line 1]

17. As to **Claim 26**, Lisiecki teaches the arrangement of Claim 25. **Wherein the second and third of the three electrodes are used to measure NMT response,** is merely a statement of intended use and does not further limit the claims. In any event, Lisiecki teaches the arrangement of Claim 25, *"these clips can also be used for acquisition of electroencephalographic and neuromuscular signals from a human subject."* [Column 6, Line 66 – Column 7, Line 1]. Furthermore it is possible to one additional electrode to be located in the area described in Claim 26.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. As to **Claims 7, 8 and 9**, the limitation **an optical sensor that is capable of being attached to the forehead, to the root of the nose, or to the ear,** is rejected over Lisiecki in view of applicants admitted prior art. The applicant teaches in the specification that is well known in the art to provide *"In transmission oximetry the emitter (two LEDs) and receiver (photodetector) are placed facing each other typically of each side of a finger, toe or earlobe. In reflectance oximetry the light is reflected below the tissue (e.g., Chest, forehead, limbs) back to the same surface as the emitter."* [Paragraph 0003] Therefore, it would have been a matter of design choice to make the pulse oximeter taught by Lisiecki to be capable of being attached to the forehead, to the root of the nose, or the ear, as choosing any of these embodiments would be equivalent over another similar optical device that is capable of being placed on a finger, toe, earlobe or any other body part.

20. **Claims 11-32** are rejected under 35 U.S.C. 102(b) as anticipated by Lisiecki or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lisiecki in view of Duckert, US 6,389,312, B1, hereinafter referred to as "Duckert."

21. As to **Claims 11,14 and 16** Lisiecki teaches, **a sensor arrangement,** *"portable integrated physiological monitoring system"* that includes: **a base element,** *"a chassis of electronic components (electronics unit) that acquisitions information from the sensors and communicates this information to a portable personal computer"* [Column 3, Line 67 – Column 4, Line 3]; **an array of electrodes,** *"a plethora of physiological sensors and auxiliary devices"* [Column 3, Lines 66-67]; **an optical sensor,** *"a finger pulse oximeter, 110,"* [Column 7, Lines 5-6]; and **are connected to a series of connectors attached to the base element,** [*See FIG 1.*] Lisiecki further teaches **wherein a first and a second electrode of the array of electrodes are NMT stimulus electrodes,** *"Alligator clips, 106, consist of ten miniature alligator clips that attach to a human subject via disposable tab electrodes. These clips can also be used for acquisition of... neuromuscular signals from a human subject. Alligator clips, 108, consist of two miniature alligator clips that attach to a human subject via disposable tab electrodes. These clips apply high voltage pulses to the human subject stimulation associated with nerve conduction studies."* [Column 6, Line 62 – Column 7, Line5 & See FIG 1] What Lisiecki does not teach however, is **a mechanical NMT sensor.** Duckert teaches a "method and system having simplified neuromuscular transmission scoring," that includes "at least one input, 32, connected to a transducer, 34, such as an accelerometer, strain gage, piezo film, etc." [Column 4, Lines 16-17] Therefore, it would

have been obvious to one with ordinary skill in the art at the time of the invention to modify the arrangement taught by Lisiecki to include the mechanical NMT transducer taught by Duckert, as it would have been a substitution for one known equivalent sensor for another. It is noted that it would be possible to locate such a sensor in the locations described, and therefore they do not form a basis for limitation of this claim.

22. As to **Claims 12**, Lisiecki teaches the arrangement of claim 11, **wherein a first and a second electrode of the array of electrodes are NMT stimulus electrodes,** *"Alligator clips, 106, consist of ten miniature alligator clips that attach to a human subject via disposable tab electrodes. These clips can also be used for acquisition of... neuromuscular signals from a human subject. Alligator clips, 108, consist of two miniature alligator clips that attach to a human subject via disposable tab electrodes. These clips apply high voltage pulses to the human subject stimulation associated with nerve conduction studies."* [Column 6, Line 62 – Column 7, Line5 & See FIG 1] It is noted that while the specific placement of the disposable electrode tabs and corresponding alligator clips are not taught, that it is possible to arrange the same in the manner described in Claim 12.

23. **Claims 13 and 15** are rejected as Lisiecki teaches the arrangement of Claims 11 or 12, and as the limitation, **wherein three of the electrodes of the array of electrodes are used to measure EEG and EMG,** merely states an intended use of the structure. That aside, Lisiecki teaches, *"FIGS. 1 and 2 show only three of these clips for illustrative purposes however, ten of them are required for acquisition of a 12-lead electrocardiogram. These clips can also be used for acquisition of*

electroencephalographic and neuromuscular signals from a human subject." [Column 6, Line 64 – Column 7, Line 1] It is noted that while the specific placement of the disposable electrode tabs and corresponding alligator clips are not taught, that it is possible to arrange the same in the manner described in Claim 13 or Claim 15.

24. As to **Claims 17, 18 and 19**, the limitation **an optical sensor that is capable of being attached to the forehead, to the root of the nose, or to the ear,** is rejected over Lisiecki in view of applicants admitted prior art. The applicant teaches in the specification that is well known in the art to provide *"In transmission oximetry the emitter (two LEDs) and receiver (photodetector) are placed facing each other typically of each side of a finger, toe or earlobe. In reflectance oximetry the light is reflected below the tissue (e.g., Chest, forehead, limbs) back to the same surface as the emitter."* [Paragraph 0003] Therefore, it would have been a matter of design choice to make the pulse oximeter taught by Lisiecki to be capable of being attached to the forehead, to the root of the nose, or the ear, as choosing any of these embodiments would be equivalent over another similar optical device that is capable of being placed on a finger, toe, earlobe or any other body part.

25. As to **Claim 20**, Lisiecki teaches the arrangement of Claim 11, **wherein the optical sensor is a SpO2 sensor.** FIG 1 clearly indicates that sensor 110 is a connected to a SpO2 terminal. [See FIG 1.]

26. As to **Claims 27, 30 and 32**, Lisiecki teaches, **a sensor arrangement,** *"portable integrated physiological monitoring system"* that includes: **a base element,** *"a chassis*

of electronic components (electronics unit) that acquisitions information from the sensors and communicates this information to a portable personal computer" [Column 3, Line 67 – Column 4, Line 3]; **an array of electrodes,** *"a plethora of physiological sensors and auxiliary devices"* [Column 3, Lines 66-67]; **an optical sensor,** *"a finger pulse oximeter, 110,"* [Column 7, Lines 5-6]; and **are connected to a series of connectors attached to the base element,** [*See FIG 1.*] Lisiecki further teaches **wherein a first and a second electrode of the array of electrodes are NMT stimulus electrodes,** *"Alligator clips, 106, consist of ten miniature alligator clips that attach to a human subject via disposable tab electrodes. These clips can also be used for acquisition of... neuromuscular signals from a human subject. Alligator clips, 108, consist of two miniature alligator clips that attach to a human subject via disposable tab electrodes. These clips apply high voltage pulses to the human subject stimulation associated with nerve conduction studies."* [Column 6, Line 62 – Column 7, Line5 & See FIG 1] What Lisiecki does not teach however, is **a mechanical NMT sensor.** Duckert teaches a "method and system having simplified neuromuscular transmission scoring," that includes "at least one input, 32, connected to a transducer, 34, such as an accelerometer, strain gage, piezo film, etc." [Column 4, Lines 16-17] Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to modify the arrangement taught by Lisiecki to include the mechanical NMT transducer taught by Duckert, as it would have been a substitution for one known equivalent sensor for another. It is noted that it would be possible to locate such a sensor in the locations described, and therefore they do not form a basis for limitation of this claim.

27. As to **Claim 28**, Lisiecki teaches the arrangement of Claim 27, **wherein a first and a second electrode of the array of electrodes are NMT stimulus electrodes,** *"Alligator clips, 106, consist of ten miniature alligator clips that attach to a human subject via disposable tab electrodes. These clips can also be used for acquisition of... neuromuscular signals from a human subject. Alligator clips, 108, consist of two miniature alligator clips that attach to a human subject via disposable tab electrodes. These clips apply high voltage pulses to the human subject stimulation associated with nerve conduction studies."* [Column 6, Line 62 – Column 7, Line5 & See FIG 1] It is noted that while the specific placement of the disposable electrode tabs and corresponding alligator clips are not taught, that it is possible to arrange the same in the manner described in Claim 28.

28. **Claims 29 and 31** are rejected as Lisiecki teaches the arrangement of Claims 27 or 28, and as the limitation, **wherein three of the electrodes of the array of electrodes are used to measure EEG and EMG,** merely states an intended use of the structure. That aside, Lisiecki teaches, *"FIGS. 1 and 2 show only three of these clips for illustrative purposes however, ten of them are required for acquisition of a 12-lead electrocardiogram. These clips can also be used for acquisition of electroencephalographic and neuromuscular signals from a human subject."* [Column 6, Line 64 – Column 7, Line 1] It is noted that while the specific placement of the disposable electrode tabs and corresponding alligator clips are not taught, that it is possible to arrange the same in the manner described in Claim 29.

Conclusion

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. Rantala, US 4,595,018;

b. Westenskow et al., US 5,131,401;

c. Bennett et al., US 6,625,481 B2; and

d. Tung, US 6,454,728 B1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vikram P. Sundararaman whose telephone number is 571-272-3351. The examiner can normally be reached on M-F, 830 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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VPS